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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/680,228	10/06/2000	John Albert Ellis	454313-2340.2	1613

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FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER
FOLEY, SHANON A

ART UNIT	PAPER NUMBER
1648	16

DATE MAILED: 07/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/680,228	ELLIS ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2002 and 10 May 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *4-6,8,12-16,30,35,36,42,65-81 and 94-107* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,17-19,21,23-28,31,32,43-60,62,63 and 82-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☒ Interview Summary (PTO-413) Paper No(s). *17* .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4-6,8,12-19,21,23-28,30-32,35,36,42-60,62,63,65-90 and 94-107.

DETAILED ACTION

Applicant amended claims 1, 2, 17-19, 21, 24, 26, 27, 31, 32, 43, 44, 46-51, 54-60, 64, added new claims 82-93, and cancelled claims 3, 7, 9-11, 20, 22, 29, 33, 34, 37-41 in paper no. 13. In paper no. 15, applicant amended claims 1, 2, 21, 31, 32, 50, 51, 60-63, 82-90, added new claims 94-107 and cancelled claims 61, 64, 91-93. Claims 1, 2, 4-6, 8, 12-19, 21, 23-28, 30-32, 35, 36, 42-60, 62, 63, 65-90, 94-107 are pending. Claims 4-6, 8, 12-16, 30, 35, 36, 42, 65-81 are withdrawn from consideration due to a non-election of invention. Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62, 63, 82-90, and 94-107 are under consideration.

It is noted in the remarks section on page 8 of applicant's response in paper no. 13, that applicant states that claim 61 is amended. There was no marked-up version of the claim amendment provided. However, since applicant cancelled claim 61 is paper no. 15, this inconsistency has been corrected.

It is most appreciated that applicant specifically points to page and line number to support claim amendments presented in paper no. 15.

Election/Restrictions

This application contains claims 4-6, 8, 12-16, 30, 35, 36, 42, 65-81 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Newly submitted claims 94-107 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: The claims are drawn to a composition comprising a vector encoding a PCV-2-specific epitope. Group VI of the

restriction requirement of paper no. 4 is drawn to a composition comprising a vector expressing an epitope of PCV-2. Therefore, newly presented claims 94-107 encompass patentably distinct subject matter previously indicated in the restriction requirement.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 94-107 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Double Patenting

Applicant states that the instant claims 4-6, 8, 35, 36, 42, and 65-81 are drawn to non-elected subject matter and therefore, no conflict exists between this application and 09/583,350.

Applicant's arguments have been considered, but are found unpersuasive since the claims of 09/583,350 in conflict with the instant application are also withdrawn due to a non-elected invention. 37 CFR 1.78(b) requires elimination of conflicting claims from all but one application unless good and sufficient reason for their retention during pendency is indicated. Since applicant has not supplied any reason for retaining the claims in either application, applicant is required to either cancel the conflicting claims from all but one application, see MPEP § 822.

The previous obvious-type double patenting rejection between the instant claims and some of the claims in previously co-pending application, 09/161,092 is now vacated. The '092 application, now US Patent 6,391,314 B1, does not encompass reducing disease caused by PCV-2. Therefore, it is agreed that there is no overlap between the claimed subject matter in the instant application and the patent.

Claim Objections

Claims 88-90 are objected to because of the following informalities: The claims are dependent upon claim 94, which is withdrawn from consideration due to a non-election of invention.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62, 63, 82-90 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims have been amended to incorporate PCV-2 polypeptides and/or PCV-2 antigens to elicit and immune response and reduce specific pathologies. The elected invention under examination is drawn to a composition comprising a vector encoding immunogens. Although there is a distinction in the art between immunogens and antigens (see the citation of Cruse et al. provided with the previous Office action), it cannot be determined whether the instant PCV-2 polypeptides are eliciting an immunogenic response as apposed to an antigenic response induced by the PCV-2 antigens. Further, although support for all thirteen polypeptides encoded by PCV-2 are disclosed on page 24, it cannot be determined which substances derived from PCV-2 would be considered antigens capable of antibody binding, i.e. antigenic properties.

Claims 24-28 and 54-59 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons of record.

Applicant argues on page 10 of paper no. 13 support for where the ORFs are derived is discussed on page 19, line 23.

Applicant's arguments and a review of page 19, line 23 are not persuasive since there is no mention of ORFs in the disclosure on page 19, line 23. However, in the sentence bridging pages 19 and 20 and the first full paragraph on page 20 (line numbers are not indicated in the specification), the specification discusses that the ORFs are derived from PCV-2. However, the ORF's in the claims are ambiguous. It is suggested that applicant append, "of a porcine circovirus type 2 strain" to claims 24, 25, 54, and 55 to obviate this rejection.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62, 63, 82-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Applicant cites *In re Edwards* and argues that the application need not describe the application *ipsis verbis*, and that all that is required is that the application convey that the inventor had possession of the claimed invention at the time of filing. Applicant argues that the

results of in the working examples show reduced viral load, which is indicative of an immune response.

Applicant's arguments as well as a review of the cited case law have been considered, but are found unpersuasive in part. It is fully agreed by the examiner that *ipsis verbis* support for claim language is not required in a disclosure so long as the claimed concepts and limitations are fully supported by the originally filed specification. Specific support for PCV-2 polypeptides is found on page 24. It is also agreed that an immune response is elicited in the examples incorporating specific ORFs encoding PCV-2 polypeptides into vectors administered to piglets although only reduced viremia is indicated. However, the claims encompass PCV-2 antigens. Antigen function is defined as substances which bind antibodies, see the citation of Cruse et al. provided in the previous action. The specification does not describe the structural characteristics required of PCV-2 substances that perform the required function. A definition by function alone "does not suffice, to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." Eli Lily, 119 F.3 at 1568, 43 USPQ2d at 1406. The skilled artisan would be unable to structurally identify which PCV-2 derived substances would be capable of the required function of reducing disease, especially since there is no data regarding the nature of the immune response in the piglets. Therefore, it is determined that the disclosure lacks adequate written description for PCV-2 antigens.

Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62, 63, 82-90 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for reasons of record.

Applicant argues that the declaration provided in the Charreyre Declaration and the data is the instant disclosure demonstrates that PCV-2 elicits the desired immune response in piglets. Applicant outlines *In re Wands* and asserts that the undue experimentation does not exist to practice the invention because the quantity of experimentation is low, the amount of direction is high, the working examples are present, the relative skill in the art is high, and the predictability is also high. In paper no. 15, applicant points to support for reduction of lymph node lesions, duration of viral excretion in co-pending applications. Applicant also reminds the examiner of the subject matter of other applications recently issued.

In response, various cites of support for enabling data in other applications is not present in the instant application and cannot be properly considered enabling disclosure for the present application since the data referred to is absent. Furthermore, the subject matter in the issued patents do not relate to the issues in the instant case. Applicant's arguments as well as a thorough review of the Charreyre Declaration and *In re Wands* have been considered, but are found unpersuasive. Although the declaration provided by Dr. Charreyre clearly demonstrates antibody titer and low viral secretion upon challenge in the vaccinated group, the declaration does not obviate the deficiencies present in the Wands analysis discussed in the previous action. Some of the instant claims require a vector encoding a PCV-2 polypeptide to elicit an immune response to reduce PCV-2-caused pathologies. The declaration discusses administering an inactivated PCV-2 virus. Therefore, it cannot be determined which polypeptide is required for lower viral secretion. The remaining claims require a vector encoding a PCV-2 antigen to elicit an immune response to reduce PCV-2-caused pathologies. Although the inactivated PCV-2 virus used in the declaration would be categorized as an antigen, the data does not indicate that

the antigen is effective in reducing PCV-2-caused myocarditis, and/or abortion, and or intrauterine infection, even in view of the immune response elicited. There is no indication in the declaration that the piglets developed these pathologies and there is also no data that would indicate that such ailments would be reduced upon administration of the composition. In addition, ¾ of the vaccinated population still had viral load in the mediastinal lymph nodes and half had necroscopy lesions at the conclusion of the study. The skilled artisan would not be able to predict how administering the instant compositions by the claimed methods would affect a pig experiencing the illnesses in the claims.

The declaration does not obviate the deficiencies discussed in the previous action and the rejection is maintained for reasons of record. Due to the scope of the claims drawn to reducing certain pathologies associated with PCV-2 in any pig with any PCV-2 antigen, the lack of guidance provided by the inventor drawn to identifying PCV-2 antigens or what types of immune responses are elicited by these PCV-2 antigens and polypeptides, the lack of guidance provided by the inventor as to how these immune responses aid in reducing PCV-2 disease in any pig, the small number of total subjects in the experiments, the lack of description determining what type of piglets were administered the vectors, the lack of data concerning how many received the placebo or the booster, and the lack of any significant difference observed in the pathology of the treated and untreated piglets in example 10, the lack of data collected for other evidence of PCV-2-associated disease in example 11, the lack of examples drawn to treating infected pigs, the lack of data in the declaration drawn reducing PCV-2 associated ailments in the claims, the state of the art that fails to specifically point to the cause in the sudden emergence of PCV-2 disease, the lack of art teaching PCV-2 disease amelioration or prevention, the unpredictable nature of

vaccine development, the lack of predictability for the skilled artisan to identify any PCV-2 antigen used to treat or prevent PCV-2 disease, it is determined that undue experimentation would be required of one skilled in the art to reduce any PCV-2-associated disease or pathology with any generic plasmid expressing any ORF from PCV-2 or immunogen.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (703) 308-3983. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (703) 308-4027. The fax phone numbers for the

organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Shanon Foley/SAF
July 13, 2002

James C. Housel 7/15/02
JAMES HOUSEL
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600